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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/708,306	11/07/2000	Li-Wei Hsu	205032000400	1255

7590 03/13/2002

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EXAMINER
GABEL, GAILENE

ART UNIT	PAPER NUMBER
1641	3

DATE MAILED: 03/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/708,306	Applicant(s) HSU ET AL.	
	Examiner Gailene R. Gabel	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims

1. Claims 1-13 are pending and are currently under examination.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> It does not state that the persons making the oath or declaration have reviewed and understand the contents of the specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration.

Specifically, the oath or declaration lists joint inventors and requires that both inventors have reviewed and understand the contents of the specification, including the claims.

Drawings

3. This application has been filed with informal drawings which are acceptable for examination purposes only. The drawings in this application are also objected to by the Draftsperson (see PTO-948 attached). Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in reciting, "capable of binding" because it fails to recite a positive limitation in the claim.

Claim 1 is confusing in reciting, "adding a labeled target ... in the crude extract onto the support" because it is unclear which element the labeled target is "added to" so as to bind biologically active ingredients. It is further confusing in relation to the previous "fractionating" step because it is unclear as to whether "the crude extract" is, indeed, fractionated on the support. It appears that the "crude extract" in step 1 is physically the same as "the crude extract" in step 2 of the claim.

Claim 1 is vague and indefinite in reciting, "detecting and recovering the biologically active ingredients" because it fails to distinctly define how the "detecting" and "recovering" steps are effected. Consequently, claim 1 is incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. Specifically, claim 1 fails to recite that the claimed labeled target binds to biologically active ingredient(s) of interest fractionated on the solid support then detecting the resulting complex formed comprising the labeled target and the biologically active ingredient(s).

Claim1 is incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. Specifically, claim 1 fails to

account for and distinctly define how unbound "labeled target" and unbound "biologically active ingredients" are separated from those that bind in the detection step.

Same analogous comments and problems in the detecting step, apply to the "recovering step".

In claim 2, "a herb" should be "an herb".

Claim 7 is vague, indefinite, confusing, and lacks clear antecedent basis in reciting, "one of the biologically active ingredients is a small molecule ... " in relation to claims 1-6 from which it depends, in the alternative, because it is unclear how this small molecule is differentially fractionated, differentially bound to the labeled target, differentially detected, and differentially recovered from all the other biologically active ingredients that have been fractionated, bound to the labeled target, detected, and recovered.

Claim 11 is vague and indefinite in reciting, "gridded components ... that are fractionated from an extract of plant" because it is unclear what is encompassed by the recitation. Specifically, it is unclear as to whether the "gridded components" are part of the kit or a resultant component in a method for use of the kit. Please clarify.

Claim 11 lacks antecedent support in reciting, "the reagents".

Claim 11 is vague, indefinite, and incomplete in reciting what appears to be uses of elements in a kit, i.e. "for probe hybridization, washing, detecting, selecting, and recovering..." rather than components of the kit itself.

In claim 12, "a herb" should be "an herb".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. Claims 1, 4, and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Burmer (US 6,087,103).

Burmer discloses a high throughput screening method for simultaneously identifying multiple biologically active ingredients (ligands or pharmacological compounds, i.e. small organic molecules) that bind or interact with multiple targets in an array (see column 1, line 47 to column 2, line 5 and column 3, lines 20-37). The targets are proteins expressed from a cDNA library and are bound to a solid support (see column 2, lines 17-33). Each library is arrayed spatially into gridded components on a solid support, i.e. in a matrix such as a microtiter dish (see column 3, lines 39-46). After the binding interaction between the biologically active ingredients and the target protein, the mixture is washed and the binding is determined by identifying a detectable moiety associated with the complex formation (see column 3, line 62 to column 4, line 9). Burmer discloses kits for use in the method including the solid support, wash reagents, label/tags for the ligand, and specific instruction for use with the method (see column 15, lines 8-24).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burmer (US 6,087,103).

Burmer discloses a high throughput screening method for simultaneously identifying multiple biologically active ingredients (ligands or pharmacological compounds, i.e. small organic molecules) that bind or interact with multiple targets in an array (see column 1, line 47 to column 2, line 5 and column 3, lines 20-37). The targets are proteins expressed from a cDNA library and are bound to a solid support (see column 2, lines 17-33). Each library is arrayed spatially into gridded components on a solid support, i.e. in a matrix such as a microtiter dish (see column 3, lines 39-46). After

the binding interaction between the biologically active ingredients and the target protein, the mixture is washed and the binding is determined by identifying a detectable moiety associated with the complex formation (see column 3, line 62 to column 4, line 9). Burmer discloses kits for use in the method including the solid support, wash reagents, label/tags for the ligand, and specific instruction for use with the method (see column 15, lines 8-24).

Burmer differs from the instant invention in failing to disclose that the biologically active ingredient screened and obtained in the method is a small molecule with a molecular weight of 268 gm/mole and is self-polymerizable.

It is, however, maintained that molecular weight, i.e. small organic molecules or 268 gm/mole, and other properties, i.e. self-polymerizable, of an isolated active compound are inherent properties of the compounds that can be identified using routine optimization procedures. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). Since Applicant has not disclosed that the specific limitations recited in instant claims 7 and 8 are for any particular purpose or solve any stated problems, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable values or properties of the methods disclosed by Burmer by normal optimization procedures.

7. Claims 2-3 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burmer (US 6,087,103) in view of Baek et al. (Agricultural Chemistry and Biotechnology, April 1998 (Abstract)).

Burmer discloses a high throughput screening method for simultaneously identifying multiple biologically active ingredients (ligands or pharmacological compounds, i.e. small organic molecules) that bind or interact with multiple targets in an array (see column 1, line 47 to column 2, line 5 and column 3, lines 20-37). The targets are proteins expressed from a cDNA library and are bound to a solid support (see column 2, lines 17-33). Each library is arrayed spatially into gridded components on a solid support, i.e. in a matrix such as a microtiter dish (see column 3, lines 39-46). After the binding interaction between the biologically active ingredients and the target protein, the mixture is washed and the binding is determined by identifying a detectable moiety associated with the complex formation (see column 3, line 62 to column 4, line 9). Burmer discloses kits for use in the method including the solid support, wash reagents, label/tags for the ligand, and specific instruction for use with the method (see column 15, lines 8-24).

Burmer differs in failing to disclose that the biologically active ingredients is specifically extracted from Carthamus tinctorius L.

Baek et al. teach extracting and fractionating biologically active compounds from Carthamus tinctorius L. Two biologically active flavonoid compounds have been isolated by repeat silica gel column chromatographies.

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to screen an extract of the plant C. tinctorius L. for biologically active compounds and isolate these active compounds as taught by Baek using the high throughput screening method taught by Burmer because Burmer specifically taught application of his simultaneous screening method for pharmacological compounds including those comprising small organic molecules such as C. Tinctorius L. as in the teaching of Baek.

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burmer (US 6,087,103) as applied to claims 7-8 above, in view of Verma et al. (Journal of Medicinal and Aromatic Plant Sciences, September 1997).

Burmer has been discussed supra. Burmer differs in failing to teach that the small molecule exhibits antithrombotic activity.

Verma et al. teach extracting and isolating biologically active compounds from Carthamus tinctorius L. According to Verma et al., these biologically active compounds from Carthamus tinctorius L. have antithrombotic capacity (see page 738 and 740).

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to screen an extract of plant for biologically active compounds using the high throughput screening method taught by Burmer, and isolate these active compounds for identification of specific inherent properties, i.e. antithrombotic activity, such as taught by Verma in evaluating pharmacological properties of the species Carthamus tinctorius L., because Burmer specifically taught application of his

simultaneous screening method for pharmacological compounds including those from plants comprising small organic molecules such as C. Tinctorius L. as in the teaching of Verma.

9. Claims 5-6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burmer (US 6,087,103), as applied to claims 4 and 7-8 above, in view of Kutsuna et al. (Journal of the Pharmaceutical Society of Japan, November, 1988) (Abstract)).

Burmer has been discussed supra. Burmer differs from the instant invention in failing to teach that the small molecule exhibits an inhibition activity in platelet aggregation for target proteins such as glycoprotein IIb/IIIa.

Kutsuna et al. identify and determine a biologically active ingredient from safflower Carthamus tinctorius L. The biologically active ingredient is a platelet aggregation inhibitor affecting platelet membrane receptor glycoprotein IIb/IIIa. This inhibitor is isolated by high performance liquid chromatography (HLPC).

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to screen an extract of plant for biologically active compounds using the high throughput screening method taught by Burmer, and isolate these active compounds for identification of specific inherent properties, i.e. platelet aggregation inhibition, such as taught by Kutsuna in evaluating pharmacological properties of the species Carthamus tinctorius L., because Burmer specifically taught application of his simultaneous screening method for pharmacological compounds including those from

plants comprising small organic molecules such as C. Tinctorius L. as in the teaching of Kutsuna.

11. No claims are allowed.

Remarks

12. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

Southern et al. (Current Opinion in Biology, 1996) teach techniques and applications of high density gridding technology.

Kim et al. (US 5,681,823) disclose P^1, P^4-dithio-P^2, P^3-monochloromethylene 5', 5'"- diadenosine P^1,P^4- tetraphosphate which is a composition that is ubiquitous in living cells and has a potent platelet aggregation inhibitory effect.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R Gabel whose telephone number is (703) 305-9297. The examiner can normally be reached on Monday-Thursday 6:00 AM to 3:30 PM and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gailene R. Gabel
March 7, 2002

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
03/10/02